

**EC-Declaration of Conformity**  
According to directive 93/42 EEC of Medical Devices

We, as manufacturer

Streifeneder ortho.production GmbH  
Moosfeldstrasse 10  
82275 Emmering/Germany

declare in sole responsibility, that successive named Medical Devices

<b>Product:</b>	Braces
<b>Class:</b>	I
<b>Nomenclature term:</b>	Orthopedic Brace
<b>Nomenclature code - UMDNS:</b>	----

be up to standard of all requirements to the directive 93/42 EEC.

<b>Evaluation method of conformity:</b>	Annex VII, to directive 93/42 EEC
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<b>EC-Declaration of Conformity is valid until:</b>	13. November 2015
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<b>Place and date of issue:</b>	Emmering, 2. August 2013
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<b>Name, Position:</b>	Michael Leitmair, Managing Director
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Signature

## EC-Declaration of Conformity according to directive 93/42 EEC of Medical Devices

Annex to: Orthopedic Brace - "Brace", Part 1: "Max"-Braces  
effective from 2. August 2013, valid until 13. November 2015

Item-Number	article description
13B1/L	Lumbomax for women, size L (IV)
13B1/M	Lumbomax for women, size M (III)
13B1/S	Lumbomax for women, size S (II)
13B1/XL	Lumbomax for women, size XL (V)
13B1/XS	Lumbomax for women, size XS (I)
13B1/XXL	Lumbomax for women, size XXL (VI)
14B1/L	LumboMax for men, size L (IV)
14B1/M	LumboMax for men, size M (III)
14B1/S	LumboMax for men, size S (II)
14B1/XL	LumboMax for men, size XL (V)
14B1/XS	LumboMax for men, size XS (I)
14B1/XXL	LumboMax for men, size XXL (VI)
14B2	Terry cover for dorsal pad, light grey
15B1/L	LumboMax for women, size L (IV)
15B1/M	LumboMax for women, size M (III)
15B1/S	LumboMax for women, size S (II)
15B1/XL	LumboMax for women, size XL (V)
15B1/XS	LumboMax for women, size XS (I)
15B1/XXL	LumboMax for women, size XXL (VI)
15B2	Terry cover for dorsal pad, skin-colored
17B1/L	GenuMax, Knee Brace, flesh, size large
17B1/M	GenuMax, Knee Brace, flesh, size medium
17B1/S	GenuMax, Knee Brace, flesh, size small
17B1/XL	GenuMax, Knee Brace, flesh, size extra large
17B1/XS	GenuMax, Knee Brace, flesh, size extra small
17B1/XXL	GenuMax, Knee Brace, flesh, size xx-large
19B1/LL	MalleoMax ankle support, flesh, left, size large
19B1/LM	MalleoMax ankle support, flesh, left, size medium
19B1/LS	MalleoMax ankle support, flesh, left, size small
19B1/LXL	MalleoMax ankle support, flesh, left, size extra large
19B1/LXS	MalleoMax ankle support, flesh, left, size extra small
19B1/LXXL	MalleoMax ankle support, flesh, left, size xx-large
19B1/RL	MalleoMax ankle support, flesh, right, size large
19B1/RM	MalleoMax ankle support, flesh, right, size medium
19B1/RS	MalleoMax ankle support, flesh, right, size small
19B1/RXL	MalleoMax ankle support, flesh, right, size extra large
19B1/RXS	MalleoMax ankle support, flesh, right, size extra small
19B1/RXXL	MalleoMax ankle support, flesh, right, size xx-large
21B1/XL	Epimax, skin coloured, size XL
21B1/XS	Epimax, skin coloured, size XS
21B1/XXL	Epimax, skin coloured, size XXL
22B1/L	GenuMax, Knee Brace, size large
22B1/M	GenuMax, Knee Brace, size medium
22B1/S	GenuMax, Knee Brace, size small
22B1/XL	GenuMax, Knee Brace, size extra large

Item-Number	article description
22B1/XS	GenuMax, Knee Brace, size extra small
22B1/XXL	GenuMax, Knee Brace, size xx-large
23B1/LL	MalleoMax, silver/anthracite, left, size L
23B1/LM	MalleoMax, silver/anthracite, left, size M
23B1/LS	MalleoMax, silver/anthracite, left, size S
23B1/LXL	MalleoMax, silver/anthracite, left, size XL
23B1/LXS	MalleoMax, silver/anthracite, left, size XS
23B1/LXXL	MalleoMax, silver/anthracite, left, size XXL
23B1/RL	MalleoMax, silver/anthracite, right, size L
23B1/RM	MalleoMax, silver/anthracite, right, size M
23B1/RS	MalleoMax, silver/anthracite, right, size S
23B1/RXL	MalleoMax, silver/anthracite, right, size XL
23B1/RXS	MalleoMax, silver/anthracite, right, size XS
23B1/RXXL	MalleoMax, silver/anthracite, right, size XXL
26B1/L	GenuMax.luxus, Knee Brace, size large
26B1/M	GenuMax.luxus, Knee Brace, size medium
26B1/S	GenuMax.luxus, Knee Brace, size small
26B1/XL	GenuMax.luxus, Knee Brace, size extra large
26B1/XS	GenuMax.luxus, Knee Brace, size extra small
26B1/XXL	GenuMax.luxus, Knee Brace, sitze xx-large
26B1/XXS	GenuMax.luxus, Knee Brace, size xx-small
27B1/L	GenuMax.luxus, Knee Brace, size large
27B1/M	GenuMax.luxus, Knee Brace, size medium
27B1/S	GenuMax.luxus, Knee Brace, size small
27B1/XL	GenuMax.luxus, Knee Brace, size extra large
27B1/XS	GenuMax.luxus, Knee Brace, size extra small
27B1/XXL	GenuMax.luxus, Knee Brace, size xx-large
27B1/XXS	GenuMax.luxus, Knee Brace, size xx-small
28B1/LL	ManuMax, wrist brace, skin coloured, size large, left
28B1/LM	ManuMax, wrist brace, skin coloured, size medium, left
28B1/LS	ManuMax, wrist brace, skin coloured, size small, left
28B1/LXL	ManuMax, wrist brace, skin coloured, size extra large, left
28B1/LXS	ManuMax, wrist brace, skin coloured, size extra small, left
28B1/LXXL	ManuMax, wrist brace, skin coloured, size xx-large, left
28B1/RL	ManuMax, wrist brace, skin coloured, size large, right
28B1/RM	ManuMax, wrist brace, skin coloured, size medium, right
28B1/RS	ManuMax, wrist brace, skin coloured, size small, right
28B1/RXL	ManuMax, wrist brace, skin coloured, size extra large, right
28B1/RXS	ManuMax, wrist brace, skin coloured, size extra small, right
28B1/RXXL	ManuMax, wrist brace, skin coloured, size xx-large, right
29B1/LL	ManuMax, wrist brace silver-anthracite, size large, left
29B1/LM	ManuMax, wrist brace silver-anthracite, size medium, left
29B1/LS	ManuMax, wrist brace silver-anthracite, size small, left
29B1/LXL	ManuMax, wrist brace silver-anthracite, size extra large, left
29B1/LXS	ManuMax, wrist brace silver-anthracite, size extra small, left
29B1/LXXL	ManuMax, wrist brace silver-anthracite, size xx-large, left
29B1/RL	ManuMax, wrist brace silver-anthracite, size large, right
29B1/RM	ManuMax, wrist brace silver-anthracite, size medium, right
29B1/RS	ManuMax, wrist brace silver-anthracite, size small, right
29B1/RXL	ManuMax, wrist brace silver-anthracite, size extra large, right
29B1/RXS	ManuMax, wrist brace silver-anthracite, size extra small, right
29B1/RXXL	ManuMax, wrist brace silver-anthracite, size xx-large, right
33B1/L	EpiMax, skin coloured, size L
33B1/M	Epimax, skin coloured, size M

Item-Number	article description
33B1/S	EpiMax, skin coloured, size S
33B1/XL	EpiMax, skin coloured, size XL
33B1/XS	EpiMax, skin coloured, size XS
33B1/XXL	EpiMax, skin coloured, size XXL
33B1/XXS	EpiMax, skin coloured, size XXS
34B1/L	EpiMax, silver/anthracite, size L
34B1/M	Epimax, silver/anthracite, size M
34B1/S	EpiMax, silver/anthracite, size S
34B1/XL	Epimax, silver/anthracite, size XL
34B1/XS	EpiMax, silver/anthracite, size XS
34B1/XXL	EpiMax, silver/anthracite, size XXL
34B1/XXS	EpiMax, silver/anthracite, size XXS
40B1/L	EpiMax.light, Elbow Support, flesh, size large
40B1/M	EpiMax.light, Elbow Support, flesh, size medium
40B1/S	EpiMax.light, Elbow Support, flesh, size small
40B1/XL	EpiMax.light, Elbow Support, flesh, size extra large
40B1/XS	EpiMax.light, Elbow Support, flesh, size extra small
40B1/XXL	EpiMax.light, Elbow Support, flesh, size xx-large
41B1/L	EpiMax.light, Elbow Support, size large
41B1/M	EpiMax.light, Elbow Support, size medium
41B1/S	EpiMax.light, Elbow Support, size small
41B1/XL	EpiMax.light, Elbow Support, size extra large
41B1/XS	EpiMax.light, Elbow Support, size extra small
41B1/XXL	EpiMax.light, Elbow Support, size xx-large
43B1/L	MalleoMax.light, flesh, size large
43B1/M	MalleoMax.light, flesh, size medium
43B1/S	MalleoMax.light, flesh, size small
43B1/XL	MalleoMax.light, flesh, size extra large
43B1/XS	MalleoMax.light, flesh, size extra small
43B1/XXL	MalleoMax.light, flesh, size xx-large
44B1/L	MalleoMax.light, silver/anthracite, size large
44B1/M	MalleoMax.light, silver/anthracite, size medium
44B1/S	MalleoMax.light, silver/anthracite, size small
44B1/XL	MalleoMax.light, silver/anthracite, size extra large
44B1/XS	MalleoMax.light, silver/anthracite, size extra small
44B1/XXL	MalleoMax.light, silver/anthracite, size xx-large
46B1/L	GenuMax.light, knee brace, size L
46B1/M	GenuMax.light, knee brace, size M
46B1/S	GenuMax.light, knee brace, size S
46B1/XL	GenuMax.light, knee brace, size XL
46B1/XS	GenuMax.light, knee brace, size XS
46B1/XXL	GenuMax.light, knee brace, size XL
47B1/L	GenuMax.light, knee brace, size L
47B1/M	GenuMax.light, knee brace, size M
47B1/S	GenuMax.light, knee brace, size S
47B1/XL	GenuMax.light, knee brace, size XL
47B1/XS	GenuMax.light, knee brace, size XS
47B1/XXL	GenuMax.light, knee brace, size XXL
50B1/LL	AchilloMax, left side, size L
50B1/LM	AchilloMax, left side, size M
50B1/LS	AchilloMax, left side, size S
50B1/LXL	AchilloMax, left side, size XL
50B1/LXS	AchilloMax, left side, size XS
50B1/RL	AchilloMax, right side, size L

Item-Number	article description
50B1/RM	AchilloMax, right side, size M
50B1/RS	AchilloMax, right side, size S
50B1/RXL	AchilloMax, right side, size XL
50B1/RXS	AchilloMax, right side, size XS
51B1/LL	AchilloMax, left side, size L
51B1/LM	AchilloMax, left side, size M
51B1/LS	AchilloMax, left side, size S
51B1/LXL	AchilloMax, left side, size XL
51B1/LXS	AchilloMax, left side, size XS
51B1/RL	AchilloMax, right side, size L
51B1/RM	AchilloMax, right side, size M
51B1/RS	AchilloMax, right side, size S
51B1/RXL	AchilloMax, right side, size XL
51B1/RXS	AchilloMax, right side, size XS
54R1/XXS	GenuMax.stabil, Gr. XXS
54R1/XS	GenuMax.stabil, Gr. XS
54R1/S	GenuMax.stabil, Gr. S
54R1/M	GenuMax.stabil, Gr. M
54R1/L	GenuMax.stabil, Gr. L
54R1/XL	GenuMax.stabil, Gr. XL
54R1/XXL	GenuMax.stabil, Gr. XXL
65R1/L	LumboMax.easy, Gr. L
65R1/M	LumboMax.easy, Gr. M
65R1/S	LumboMax.easy, Gr. S
65R1/XL	LumboMax.easy, Gr. XL
65R1/XS	LumboMax.easy, Gr. XS
65R1/XXL	LumboMax.easy, Gr. XXL

## EC-Declaration of Conformity according to directive 93/42 EEC of Medical Devices

Annex to: Orthopedic Brace - "Brace", Part 2: Brace  
effective from 2. August 2013, valid until 13. November 2015

Item-Number	article description
60B1/L	Rib fracture and abdominal brace for woman, size L
60B1/M	Rib fracture and abdominal brace for woman, size M
60B1/S	Rib fracture and abdominal brace for woman, size S
60B1/XL	Rib fracture and abdominal brace for woman, size XL
61B1/L	Rib fracture and abdominal brace for men, size L
61B1/M	Rib fracture and abdominal brace for men, size M
61B1/S	Rib fracture and abdominal brace for men, size S
61B1/XL	Rib fracture and abdominal brace for men, size XL
74B1/LL	Hip Brace (Yale-technique), left, large
74B1/LM	Hip Brace (Yale-technique), left, medium
74B1/LS	Hip Brace (Yale-technique), left, small
74B1/RL	Hip Brace (Yale-technique), right, large
74B1/RM	Hip Brace (Yale-technique), right, medium
74B1/RS	Hip Brace (Yale-technique), right, small
74B2/LL	Inlett for art. 74B1, left, large
74B2/LM	Inlett for art. 74B1, left, medium
74B2/LS	Inlett for art. 74B1, left, small
74B2/RL	Inlett for art. 74B1, right, large
74B2/RM	Inlett for art. 74B1, right, medium
74B2/RS	Inlett for art. 74B1, right, small
110R1/L	OmoSupport.gilchrist, size L
110R1/M	OmoSupport.gilchrist, size M
110R1/S	OmoSupport.gilchrist, size S
110R1/XL	OmoSupport.gilchrist, size XL
110R1/XS	OmoSupport.gilchrist, size XS
110R1/XXL	OmoSupport.gilchrist, size XXL
120R1/L	ClaviculaSupport, size L
120R1/M	ClaviculaSupport, size M
120R1/S	ClaviculaSupport, size S
120R1/XL	ClaviculaSupport, size XL
120R1/XS	ClaviculaSupport, size XS
130T19/0B	Pavlik Harness, blue, Size 0
130T19/0R	Pavlik Harness, red, Size 0
130T19/1B	Pavlik Harness, blue, Size 1
130T19/1G	Pavlik Harness, yellow, Size 1
130T19/1R	Pavlik Harness, red, Size 1
130T19/2B	Pavlik Harness, blue, Size 2
130T19/2R	Pavlik Harness, red, Size 2
130T19/3B	Pavlik Harness, blue, Size 3
130T19/3G	Pavlik Harness, yellow, Size 3
130T19/3R	Pavlik Harness, red, Size 3
130T20/0	Pavlik Harness, Size 0
130T20/1	Pavlik Harness, Size 1
130T20/2	Pavlik Harness, Size 2
130T20/3	Pavlik Harness, Size 3
130T23/0	Pavlik Harness, Size 0
130T23/1	Pavlik Harness, Size 1
130T23/2	Pavlik Harness, Size 2

Item-Number	article description
130T23/3	Pavlik Harness, Size 3
133T3/100D	Rip Support Belt for Women, Size 100
133T3/100H	Rip Support Belt for Men, Size 100
133T3/105D	Rip Support Belt for Women, Size 105
133T3/105H	Rip Support Belt for Men, Size 105
133T3/110D	Rip Support Belt for Women, Size 110
133T3/110H	Rip Support Belt for Men, Size 110
133T3/115D	Rip Support Belt for Women, Size 115
133T3/115H	Rip Support Belt for Men, Size 115
133T3/120D	Rip Support Belt for Women, Size 120
133T3/120H	Rip Support Belt for Men, Size 120
133T3/70D	Rip Support Belt for Women, Size 70
133T3/70H	Rip Support Belt for Men, Size 70
133T3/75D	Rip Support Belt for Women, Size 75
133T3/75H	Rip Support Belt for Men, Size 75
133T3/80D	Rip Support Belt for Women, Size 80
133T3/80H	Rip Support Belt for Men, Size 80
133T3/85D	Rip Support Belt for Women, Size 85
133T3/85H	Rip Support Belt for Men, Size 85
133T3/90D	Rip Support Belt for Women, Size 90
133T3/90H	Rip Support Belt for Men, Size 90
133T3/95D	Rip Support Belt for Women, Size 95
133T3/95H	Rip Support Belt for Men, Size 95
191P4/38	Cross Brace, Size 38
191P4/40	Cross Brace, Size 40
191P4/42	Cross Brace, Size 42
191P4/44	Cross Brace, Size 44
191P4/46	Cross Brace, Size 46
191P4/48	Cross Brace, Size 48
191P4/50	Cross Brace, Size 50
191P4/52	Cross Brace, Size 52
191P4/54	Cross Brace, Size 54
191P6/17	Splayfoot Brace without pad, size 17
191P6/18	Splayfoot Brace without pad, size 18
191P6/19	Splayfoot Brace without pad, size 19
191P6/20	Splayfoot Brace without pad, size 20
191P6/21	Splayfoot Brace without pad, size 21
191P6/22	Splayfoot Brace without pad, size 22
191P6/23	Splayfoot Brace without pad, size 23
191P6/24	Splayfoot Brace without pad, size 24
191P6/25	Splayfoot Brace without pad, size 25
191P7/16	Splayfoot Brace with pad, size 16
191P7/17	Splayfoot Brace with pad, size 17
191P7/18	Splayfoot Brace with pad, size 18
191P7/19	Splayfoot Brace with pad, size 19
191P7/20	Splayfoot Brace with pad, size 20
191P7/21	Splayfoot Brace with pad, size 21
191P7/22	Splayfoot Brace with pad, size 22
191P7/23	Splayfoot Brace with pad, size 23
191P7/24	Splayfoot Brace with pad, size 24
191P7/25	Splayfoot Brace with pad, size 25
191P7/26	Splayfoot Brace with pad, size 26